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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,427	04/30/2001	David Gustafsson	3764-96	9839

7590

05/28/2002

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 05/28/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.



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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on April 18, 2002
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 3-20, 28-30 and 32 are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-13, 15-20, 28-30 and 32 are rejected.
- ☒ Claim(s) 14 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

01/844,427

★ U.S. PAT. 1996-402-4 ★

DETAILED ACTION

Claims 1, 3-20, 28-30 and 32 are pending in the application.

The obviousness-type double patenting rejection over 09/214,143 {which matured into U.S. Patent No. 6,337,394} has been overcome. Independent claim 1 in the patent states that structures IVa and IVc (under the definition of variable B) must be substituted with specific substituents represented by R³¹. In the instant claims, structures IVa and IVc (under the definition of variable B) cannot be substituted. Therefore, there is no overlap between the instant claims and the claims in the patent.

All other rejections made in the previous Office Action which do not appear below have been overcome. Arguments pertaining to rejections which have been overcome will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 does not further limit claim 1 because the compounds of claim 17 are not embraced by claim 1 (see especially definitions of D¹ and D² in claim 17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-13, 15-17, 19, 20, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohshima et al. {U.S. Pat. 5,744,487}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim thrombin inhibitors. Ohshima et al. teach thrombin inhibitors which are structurally similar to the instant claimed compounds. See in Ohshima et al., for example, formula (I) wherein A is a carbon atom, the broken lines are single bonds, R^3 is $-C(=NR^{25})NH_2$, R^{25} is hydrogen, R^2 is hydrogen, n is one, R^1 is $-D-(CH-R^5)_m-E-R^4$, wherein D is a bond, m is zero, E is ethylene, R^4 is $-OR^6$ and R^6 is hydrogen (columns 1 and 2). Also see columns 23, 51, 81, 193-196 and 227; and especially compound 42 in columns 15-16 and compounds 52, 53 and 56 in columns 17 and 18.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that of generic description.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-thrombin). One skilled in the art would have been motivated to prepare compounds embraced by the reference genus of Ohshima et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful as a thrombin inhibitor. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Response to Arguments

Applicants' arguments filed April 18, 2002 have been fully considered. In regard to the rejection of the claims under 35 U.S.C. § 112, second paragraph, Applicants argue that claim 17 is not intended to limit claim 1. In response, since claim 17 is dependent on claim 1, the

subject matter of claim 17 should be embraced by claim 1 instead of outside the scope of claim 1. Therefore, this rejection is maintained.

In regard to the rejection of the claims under 35 U.S.C. § 103, Applicants argue that none of the specific examples of Ohshima et al. fall within the scope of the claims as amended. Applicants also argue that none of the compounds of Ohshima et al. have a CH₂ spacer group, as is instantly claimed, and there is no suggestion in Ohshima et al. to provide such compounds.

All of Applicants' arguments have been considered but have not been found persuasive. Applicants claim thrombin inhibitors. Ohshima et al. teach thrombin inhibitors which are structurally similar to the instant claimed compounds.

It would appear that Applicants are arguing that in order to have a proper rejection under 35 U.S.C. § 103, the reference must disclose a specific compound (structurally the same) which would anticipate the claims under 35 U.S.C. § 102. This is not the standard used to determine an obviousness-type rejection. There must be a motivation

and suggestion in the prior art. In the instant case, the motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-thrombin). Further, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966).

Ohshima et al. do teach specific compounds which are structurally similar to the instant claimed compounds and which some also have CH₂ spacer groups. Applicants' attention is directed to compound 2 in columns 7-8; compounds 6-14 in columns 9-10; compound 42 in columns 15-16; and compounds 52, 53 and 56 in columns 17-18. For all the reasons given above, this rejection is maintained.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235, 308-0196 or 305-3290.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556, 308-4242, 305-1935 or 308-2742.

A handwritten signature in cursive script, reading "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

May 24, 2002